

REMARKS

Claims 1 and 19 are amended. Claims 1-8, 10, and 12-20 are pending. Favorable reconsideration is respectfully requested.

At the outset, Applicants thank Examiner Patterson for the helpful comments in the Outstanding Office Action to overcome the rejections therein. Further, Applicants thank Examiner Patterson for the brief helpful discussion of the present application over the telephone prior to filing this document.

The rejection of Claims 1-8, 10, and 1-20 under 35 U.S.C. § 112, first paragraph, and the new matter rejection is believed to be obviated by the above amendment combined with the remarks below.

The new matter rejection is believed to be obviated by the cancellation of the phrase "carbamoyl racemase". Accordingly, withdrawal of this ground of rejection is respectfully requested.

Applicants thank Examiner Patterson for indicating that the 112, first paragraph, rejection, may be obviated if Applicants directed the Examiner's attention to disclosures of JM 109, pOM22, and pOM21 because "the Examiner does not readily find this disclosure in the instant patent" (i.e., WO 00/58499). Applicants respectfully direct the Examiner's attention to page 10, line 23, of WO 00/58499 (WO '499), which specifically discloses *E. coli* JM109. Further, the Examiner's attention is directed to page 14, lines 14-15, of WO '499, which specifically discloses pOM22 and pOM21. Therefore, in accordance with the Examiner's suggestion, Applicants have pointed out specifically where JM109, pOM22, and pOM21 is specifically disclosed in WO '499.

In addition, the Examiner indicates that "the Examiner will consider whether to consider the data disclosed on page 7 as related to formula II" if Applicants can show that the structure of formula II is the "DL-allysine hydantoin" recited on page 7. In accordance with the Examiner's instructions, the following remarks are submitted to support Applicants' contention that the Examiner should consider the data disclosed on page 7 as related to formula II.

First, page 3, lines 5-10 of the present specification discloses that the present invention comprises the preparation of allysine acetal of the general formula I. Further, the present specification discloses at page 3, lines 10-15 that the starting material in the preparation of the allysine acetal of general formula I is a hydantoin of the general formula II, which has an acetal moiety. Still further, the present specification discloses at page 4, lines 16-17, that "the structures of the compound shown in formula (I) and (II) above relate to both optical isomers."

In light of the above, it is clear that formula II relates to "both optical isomers" which are D- and L-hydantoins. Further, the present process relates to preparation of allysine acetal of general formula I. Applicants respectfully submit the attached pages from the basic introductory organic textbook from Ralph J. Fessenden and Joan S. Fessenden entitled "Fessenden & Fessenden" (4th Edition) published by Brooks/Cole Publishing Co., copyright 1990 (see enclosed copies of cover and page 542-545). At page 542-545 of Fessenden & Fessenden attached hereto, it is demonstrated that a skilled artisan with basic organic chemistry knowledge understands what an acetal moiety would be and therefore demonstrates that the skilled artisan would understand what an allysine acetal structure entails. Moreover, Applicants specifically disclose at page 7, line 19, of the specification a result in the examples that is the production of L-allysine acetal of greater than 85% having an optical purity of

greater than 99% enantiomeric excess. Accordingly, the skilled artisan would clearly understand that the "DL-allysine hydantoin" utilized in the example contains the acetal moiety and therefore falls within formula II. There is no other possible source of the acetal moiety on the resultant L-allysine acetal product.

In addition, the Examiner indicates that the Applicants has not addressed what is meant by "N-carbamoyl amino acid". Applicants respectfully submit that this issue was not addressed because it appeared as if the Examiner understood this phrase, more specifically the compound, in light of the results of the interview held January 23, 2003. Moreover, Applicants respectfully apologize for not addressing this issue more thoroughly. Regarding this issue, Applicants respectfully direct the Examiner's attention to Syldatk et al. (1988) Ann. N.Y. Acad. Sci. 542, 323-329 which was cited in the Examiner's PTO-892 form and enclosed with the Examiner's Office Action dated November 27, 2002. The Examiner relied on this reference in order to provide a 103 rejection which has now been withdrawn. Although Applicants respectfully thank the Examiner for withdrawing the 103 rejection in light of Applicants' arguments in the last response, Applicants once again direct the Examiner's attention to page 323 of this reference which specifically discloses a structure of a D- or L-carbamoyl amino acid. Accordingly, it appears as if the skilled artisan and the Examiner would clearly understand what an N-carbamoyl amino acid represents. Of course, the "N" of N-carbamoyl amino acid is generic and can represent either of the optical isomers D or L.

In light of the above, Applicants respectfully submit that Applicants have addressed all of the Examiner's questions related to both the new matter rejections and the 112, first paragraph, rejections. More specifically, Applicants have demonstrated that support is found in WO '499. Further, Applicants have demonstrated that formula II is a hydantoin that envelopes the "DL-allysine hydantoin" recited on page 7. Moreover, Applicants have

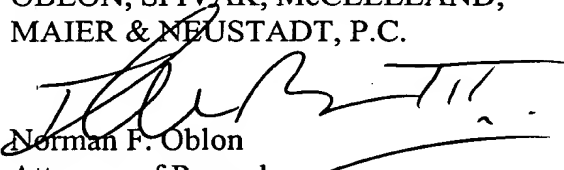
demonstrated that the skilled artisan would completely understand what a N-carbamoyl amino acid entails. Finally, Applicants demonstrate on page 7 that the *E. coli* cell strain that is utilized in the experiment is fully defined at page 5, line 26, of the present specification and within the previously provided WO '499 reference discussed above.

For all of the above reasons, the Applicants respectfully request withdrawal of the new matter and 112 rejections.

Applicants respectfully submit that the present application is now in condition for allowance. Should anything further be required to place this application in condition for allowance, the Examiner is requested to contact Applicants attorney by telephone.

Respectfully submitted,

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